DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 25 2011

Re: Metvixia
Docket No. FDA-2007-E-0104

The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This letter is in regard to the application for patent term extension for U.S. Patent No. 6,034,267 filed by PhotoCure ASA under 35 U.S.C. section 156. Please refer to the letters dated October 27, 2010, and November 2, 2010, from your Office of Patent Legal Administration. The human drug product claimed by the patent is Metvixia (methyl aminolevulinate hydrochloride), which was assigned new drug application (NDA) No. 21-415.

For the purposes of calculating whether the application for patent term extension submitted on September 20, 2004, is timely within the meaning of 35 U.S.C. section 156(d)(1), FDA confirms that the NDA for Metvixia was approved on July 27, 2004.

As noted in the October 27, 2010, letter from your Office of Patent Legal Administration, the Federal Circuit recently held that Metvixia represents the first permitted commercial marketing or use of methyl aminolevulinate hydrochloride as required by section 156(a)(5)(A) and, accordingly, that the '267 patent is eligible for extension under the provisions of section 156. A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) before its commercial marketing or use, as required under 35 U.S.C. section 156(a)(4).

We have also reviewed the dates contained in the relevant applications and have determined the regulatory review period for Metvixia. The total length of the regulatory review period for Metvixia is 1,695 days. Of this time, 659 days occurred during the testing phase and 1,036 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 8, 1999.

   The applicant claims February 24, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the testing

phase began when an earlier IND became effective on December 8, 1999, which was 30 days after FDA receipt of the earlier IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 26, 2001.

   FDA has verified the applicant's claim that the new drug application (NDA) for Metvixia (NDA 21-415) was submitted on September 26, 2001.

3. The date the application was approved: July 27, 2004.

   FDA has verified the applicant's claim that NDA 21-415 was approved on July 27, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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